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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,323	10/09/2003	Scott J. Wolf	07883.0004-07	3366

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EXAMINER

HO, UYEN T

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/681,323

Applicant(s)

WOLF ET AL.

Examiner

(Jackie) Tan-Uyen T. Ho

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52-57, 60-63 and 109-115 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52-57, 60-63 and 109-115 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/24/004.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 52-57, 60-63, 109-113 are rejected under 35 U.S.C. 102(e) as being anticipated by LaFontaine et al. (6,092,526).

LaFontaine et al. disclose a method for placing a conduit in a wall of a patient heart comprising the steps of:

In regard to claim 52 and 60:

- (a) providing a support member (124,130) and a conduit (112);
- (b) passing the support member and the conduit through an exterior wall (92) of a coronary vessel and through the wall of a patient's heart (86);
- (c) positioning the conduit within the wall of the heart (fig. 5F); and
- (d) removing the support member from the wall of the heart (col. 6, lines 55-58).

In regard to claim 53, the method of claim 52, wherein a sheath (116) overlies the conduit, and further comprising the step of moving the sheath to expose the conduit once a shaft and conduit are positioned in the wall of the heart (fig. 5F).

Art Unit: 3731

In regard to claim 54, expanding the conduit within the wall of the heart (fig. 5F)

In regard to claim 55, forming an opening (5D-5F, col. 6, lines 33-58) extending through a wall of the heart and then passing the support member through the opening (fig. 5F)

In regard to claims 56 and 61, the conduit is positioned so as to place the heart chamber in communication with the interior of the coronary vessel (fig. 5F).

In regard to claims 57 and 62, the procedure performed in the left ventricle (30)

In regard to claim 63, at least at one point, the conduit is positioned in the wall of the heart so that one end of the conduit extends partially into the heart chamber (fig. 5E).

In regard to claim 109, step (b) is carried out by passing a sharpened end of the support member (124, col. 6, lines 33-58) through the wall of the heart chamber.

In regard to claim 110:

(a) providing a transmyocardial implant delivery system with a sheath (fig. 5D)

(b) inserting the sheath through a heart wall of the heart chamber at a location offset from the coronary vessel (insert the sheath through aorta via guidewire 104) to a heart wall

(c) removing the sheath from the heart wall, leaving a hollow conduit in place within the heart wall (figs. 5E,F, col. 6, lines 33-58), a first end of the conduit in fluid communication with the heart chamber (Fig. 5F), and connecting a second end of the conduit to the coronary vessel (as the conduit advanced to the wall 92 of coronary vessel)

Art Unit: 3731

In regard to claim 111, wherein the conduit includes a rigid portion adjacent the first end within the heart wall which is sufficiently rigid to remain open during systole and diastole (inherently the stent 112 is rigid enough to maintain in opening configuration).

In regard to claim 112, the method according to claim 110, the method further comprising the steps of: providing an incision in the coronary vessel (col. 6, lines 33-58), inserting the second end of the conduit within a lumen of the coronary vessel, and securing the second end within the lumen of the coronary vessel (fig. 5F).

In regard to claim 113, the second end of the conduit is releasable held by a working end of a tool and is directed to the coronary vessel by the tool (figs. 5D-5F).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 114 and 115 are rejected under 35 U.S.C. 103(a) as being unpatentable over LaFontaine et al. (6,092,526) in view of Makower et al. (6,190,353). LaFontaine et al. disclose all the limitation of the claim except the steps of includes an anastomosis device having a flange for securing the end of the conduit to the vessel. It is well known in the art to provide an anastomosis or securing cuff having spikes/flange at an end of a prosthesis in order to better secure the stent to a vessel wall, for example, Makower et al. disclose a stent with anastomosis end having flange for secure the prosthesis to

Art Unit: 3731

vessel walls. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a securing cuff/anastomosis as disclosed by Makower et al. into LaFontaine et al.'s conduit in order to provide a better securement for the conduit.

Response to Arguments

5. Applicant's arguments filed 11/24/04 have been fully considered but they are not persuasive. Applicants argue that, LaFontaine does not disclose the step of passing the support member and the conduit through an exterior wall of a coronary vessel. Examiner disagrees. LaFontaine discloses passing the support member and the conduit through an exterior wall (92, fig. 5E, F). The support member passing through both exterior and interior of vessel wall (92) and the stent extending through the exterior of wall (92) of the coronary vessel (58) and into the interior of wall (92) such that the stent provide a flow path from the heart to the coronary vessel. Applicant also argues that LaFontaine does not teach or suggest "inserting the sheath through a heart wall of the heart chamber at a location offset from the coronary vessel." Examiner disagrees. LaFontaine discloses inserting the sheath through a heart wall via a path that is not from a coronary vessel but via a path of a guidewire 104 passing from an aorta to a heart wall (fig. 5A).

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

Art Unit: 3731

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is 571-272-4696. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANHTUAN NGUYEN can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



(Jackie) Tan-Uyen T. Ho
Patent Examiner
Art Unit 3731

February 21, 2005